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TO: Examiner ~~[illegible]~~ S. Coe
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FROM: Michael F. Krieger

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COMMENTS:

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PATENT APPLICATION
Docket No.: 10209.383
Serial No.: 10/036,152
Filed: December 31, 2001
METHOD FOR TREATING CARBON TETRA-CHLORIDE INDUCED LIVER DAMAGE BY ADMINISTERING MORINDA CITRIFOLIA

35 U.S.C. § 103 CLAIM REJECTIONS

The present invention is currently rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,039,559 (issued July 16, 1975) ("the '559 patent") and U.S. Patent Application No. 2002/0068102 (effective filing date December 1, 2000) ("the '102 application"). Examiner posits that the '559 patent teaches that carbon tetrachloride causes liver damage due to its ability to produce harmful free radicals and that the '102 application teaches that *M. citrifolia* is an antioxidant. Thus, the examiner concludes that an artisan would have a reasonable expectation of success for administering *M. citrifolia* to prevent or inhibit damage to the liver caused by carbon tetrachloride.

A "clear and particular" showing of the suggestion to combine is required to support an obviousness rejection under Section 103. MPEP § 2142. None of the references cited against the present invention contain an express suggestion to combine the references. If there was a suggestion it could only be implied, and it is the position of the Applicant that there is no "clear and particular" implied suggestion to combine. The '599 patent stands for the proposition that less cellular damage occurred in animals exposed to CC14 when they were contemporaneously exposed to α-tocopheryl pivalate. The '599 patent does not support a mechanism for the decreased damage; the '599 patent does not support the proposition that carbon tetrachloride causes liver damage due to its ability to produce harmful free radicals. The '559 patent merely suggest the "physiological damage resulting from the administration of CC14 to animals is *thought to be due* to the free radical that is brought about by the

administration." U.S. Patent No. 4,039,559, Col. 4 ln. 4-6 (emphasis added). "[T]thought to be due to" is more of a hunch than a "clear and particular" suggestion.

Applicant submits, therefore, that the prior art fails to clearly and particularly suggest the combination indicated by the Examiner. Thus, Applicant's claims are not obvious in view of the prior art references. In essence the Applicant urges that the combination of the listed references is not a product of a suggestion contained within them, but a product of inappropriate hindsight analysis. "Hindsight reconstruction" cannot be used "to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) (quoting *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988)). Rather, "the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references." *Id.* "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight." *Id.* (quoting *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999)

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